

§ 1.804

terms and conditions applicable to deposits for patent purposes. The Director may seek the advice of impartial consultants on the suitability of a depository. The depository must:

- (i) Have a continuous existence;
- (ii) Exist independent of the control of the depositor;
- (iii) Possess the staff and facilities sufficient to examine the viability of a deposit and store the deposit in a manner which ensures that it is kept viable and uncontaminated;
- (iv) Provide for sufficient safety measures to minimize the risk of losing biological material deposited with it;
- (v) Be impartial and objective;
- (vi) Furnish samples of the deposited material in an expeditious and proper manner; and
- (vii) Promptly notify depositors of its inability to furnish samples, and the reasons why.

(b) A depository seeking status under paragraph (a)(2) of this section must direct a communication to the Director which shall:

- (1) Indicate the name and address of the depository to which the communication relates;
- (2) Contain detailed information as to the capacity of the depository to comply with the requirements of paragraph (a)(2) of this section, including information on its legal status, scientific standing, staff and facilities;
- (3) Indicate that the depository intends to be available, for the purposes of deposit, to any depositor under these same conditions;
- (4) Where the depository intends to accept for deposit only certain kinds of biological material, specify such kinds;
- (5) Indicate the amount of any fees that the depository will, upon acquiring the status of suitable depository under paragraph (a)(2) of this section, charge for storage, viability statements and furnishings of samples of the deposit.

(c) A depository having status under paragraph (a)(2) of this section limited to certain kinds of biological material may extend such status to additional kinds of biological material by directing a communication to the Director in accordance with paragraph (b) of this section. If a previous communication

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under paragraph (b) of this section is of record, items in common with the previous communication may be incorporated by reference.

(d) Once a depository is recognized to be suitable by the Director or has defaulted or discontinued its performance under this section, notice thereof will be published in the Office Gazette of the Patent and Trademark Office.

§ 1.804 Time of making an original deposit.

(a) Whenever a biological material is specifically identified in an application for patent as filed, an original deposit thereof may be made at any time before filing the application for patent or, subject to § 1.809, during pendency of the application for patent.

(b) When the original deposit is made after the effective filing date of an application for patent, the applicant must promptly submit a statement from a person in a position to corroborate the fact, stating that the biological material which is deposited is a biological material specifically identified in the application as filed.

[54 FR 34880, Aug. 22, 1989, as amended at 62 FR 53202, Oct. 10, 1997]

§ 1.805 Replacement or supplement of deposit.

(a) A depositor, after receiving notice during the pendency of an application for patent, application for reissue patent or reexamination proceeding, that the depository possessing a deposit either cannot furnish samples thereof or can furnish samples thereof but the deposit has become contaminated or has lost its capability to function as described in the specification, shall notify the Office in writing, in each application for patent or patent affected. In such a case, or where the Office otherwise learns, during the pendency of an application for patent, application for reissue patent or reexamination proceeding, that the depository possessing a deposit either cannot furnish samples thereof or can furnish samples thereof but the deposit has become contaminated or has lost its capability to function as described in the specification, the need for making a replacement or supplemental deposit will be governed by the same considerations governing